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How the use of antibiotic irrigation solution affected the infection rates in penile prosthesis implantation?

Penile prosthesis infection

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Abstract

Aim: It is common practice to immerse penile implants in antibiotic solution prior to implantation. Our aim was to investigate the effect of irrigation with antibiotic solution prior to implantation of penile prostheses on surgical outcomes and infection rates.

Material and Methods: We retrospectively evaluated the data of 123 patients who underwent penile prosthesis implantation surgery at our clinic between August 2015 and August 2020. We evaluated the effect of irrigation of the prosthesis with an antibiotic solution on success and complications.

Results: The mean age of the patients was 62 years. The average length of hospital stays was 3.3 days, and the average duration of the operation was 70 minutes. Preoperative antibiotic prophylaxis included the administration of 1 g of vancomycin once a day and twice daily doses of 3rd generation cephalosporins. None of the patients experienced any perioperative complications. Of the prostheses, 83 were single-piece (Promedon), 5 were two-piece (Ambicor), 35 were three-piece (AMS 700 CXP). All prostheses were irrigated with an antibiotic solution. After surgery, 5 patients had penile pain, 1 patient had penoscrotal tenderness and itchy lesions, and 4 patients had an infection of the surgical incision site that responded to medical therapy. In addition, 3 patients required the removal of the penile prosthesis.

Discussion: Prosthesis infection may be characterized by only pain without signs of infection, or may progress to penile necrosis and loss. During the first prosthetic surgeries, urologists used a number of solutions based on their previous clinical experience to provide protection from infection. The surgical area was washed with a solution before the incision and every 15 minutes thereafter. After corporotomy, corpus cavernosum washed 3 times using this solution, and the penile prosthesis was implanted after prewashing.

Keywords

Erectile Dysfunction, Antibiotic Solution, Penile Prosthesis Implantation, Infection

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Introduction

Erectile dysfunction is defined as the persistent inability to achieve or maintain an erection adequate for satisfactory sexual activity. Its incidence in the population increases with advancing age. It has been estimated that the prevalence of erectile dysfunction of all degrees is 52% in men 40 to 70 years old with higher rates in those older than 70 years [1].

Erectile dysfunction has a significant negative impact on quality of life. Risk factors for erectile dysfunction include aging, chronic illnesses, various medications and cigarette smoking [2]. Identification of erectile dysfunction can be made through questionnaires or a complete medical and sexual history [3].

Treatment of erectile dysfunction should be carried out in steps. First of all, lifestyle changes and oral treatment should be recommended. Intraurethral treatment and a vacuum device may also be tried. Intracavernosal treatment may also be initiated if the above methods are insufficient. Penile prosthesis implantation is recommended as a third-line treatment if there is no response to the treatment in the first two steps [4]. A lot of progress has been made in penile prostheses, which are the last-line treatment, since their first use. Thus, surgical and mechanical complication rates decreased and patient-partner satisfaction levels increased [5].

Penile prosthesis infections are an extremely challenging clinical situation for surgeons and patients. The skin flora is usually the cause of the infection. Since the human skin flora contains many pathogens, a thorough physical and chemical skin cleansing is required before the surgery. Staphylococcus epidermidis is the most common causative agent of penile prosthesis infection. However, causative pathogens including E. coli, P. aeruginosa, S. marcescens, P. mirabilis and methicillin-resistant Staphylococcus aureus can also be encountered [6,7]. Prosthetic infections, which have a frequency of 1-3% in primary prosthesis applications, can increase up to 7% and 18%, respectively, in revision surgeries and additional reconstructive surgeries. The most important data regarding infection rates after prosthetic surgery is that a significant portion of implanted prostheses do not actually cause clinically typical signs of infection. One study showed a high rate of 40-80% of bacterial colonies in penile prosthesis materials removed for non-infectious reasons [8,9]. Measures to prevent the formation of penile prosthesis infections, rather than their treatment, are of great importance. First of all, it is necessary to minimize the length of hospital stay for patients scheduled for prosthesis implantation, to shave the surgical area in the operating room, and to avoid simultaneous surgeries and the use of additional synthetic materials. Before surgery, it is necessary to clean the surgical area with chlorhexidine or povidone-iodine to prevent unnecessary entry and exit to the operating room, to ensure effective control of bleeding during surgery, and to control co-morbid diseases, if any, in the pre-operative period [10,11].

In this study, we planned to evaluate the efficacy of irrigation of penile prostheses with an antibiotic solution before their implantation against infections.

Material and Methods

The study started with the ethical approval of SBU Antalya Training and Research Hospital, dated 01.10.2020 and numbered 298.

We retrospectively evaluated the data of 123 patients who underwent penile prosthesis implantation surgery in our clinic between August 2015 and August 2020. All patients underwent general physical examination before surgery. The patients underwent additional further investigations including hormonal tests, intracavernosal injection and stimulation tests, and penile color Doppler ultrasonography before deciding on surgery. Before the penile prosthesis implantation surgery, a preliminary interview was held with the patients and their partners. The patients were informed about the surgical procedure, the type, advantages and disadvantages of prostheses, and possible complications. The necessary psychosocial and sexual evaluation was performed by a psychiatrist. Preoperative evaluation included essential biochemical investigations. Normal urine analysis and culture were expected. Patients with diabetes mellitus with an HbA1c value of 6.8 and above were operated after the blood glucose level was controlled. All patients received a standard antibiotic regimen. All penile prostheses to be implanted were not checked for antibiotic coating before surgery.

Our case was taken to the operating room as the first case of the day. All patients underwent mechanical cleaning of the surgical site before surgery. Prior to the surgery, entry and exit from the operating room were restricted. The surgical field was washed with povidone iodine for 15 minutes before sterile dressing. The surgical area was then covered with a sterile drape. An antibiotic solution was prepared for surgical prophylaxis on the additional table. On an additional table, an antibiotic solution was prepared for surgical prophylaxis, containing a mixture of 2400 mg of gentamicin and 5000 mg of rifampicin in 1000 cc of isotonic saline, and 500 cc of 10% povidone-iodine. The penile prosthesis and its parts were placed in this solution and kept until implantation. The surgical area was washed with solution before the incision and every 15 minutes thereafter. After corporotomy, corpus cavernosum was washed 3 times using this solution, and the penile prosthesis was implanted after prewashing. All patients underwent spinal anesthesia. The patients were re-informed about the use of prostheses after the surgical procedure. If there was no additional precaution, the patient was allowed to use the penile prosthesis in the 6th postoperative week.

The type of prosthesis and the success and complication rates were recorded. For patients who developed complications, subsequent treatments and outcomes were evaluated.

Ethical Approval

Ethics Committee approval for the study was obtained.

Results

Demographical analysis revealed diabetes mellitus (DM) in 46 patients (37.3%), hypertension (HT) in 73 patients (59.3%), coronary artery disease (CAD) in 32 patients (26.0%), 28 smoking patients (22.7%), Peyronie's disease in 4 patients (3.2%), radiotherapy history in 6 patients (4.8%), radical prostatectomy history in 22 patients (17.8%).

Preoperative IIEF scoring showed severe ED in all patients. In addition, Doppler USG showed the highest frequency of bilateral arterial insufficiency in 90 (73.1%) patients, followed by mixed

type in 10 (8.1%) patients and left arterial insufficiency in 5 (4%) patients (Table 1).

The mean age of 123 patients who underwent penile prosthesis surgery was 62 years. The mean duration of ED was 29 months. The mean duration of hospital stay, operation, and follow-up was 3.3 days, 70 minutes, and 13 months, respectively (Table 2).

All patients underwent spinal anesthesia. All patients underwent mechanical cleaning of the surgical site before surgery. The surgical field was washed with povidone-iodine for 15 minutes before sterile dressing. During the surgery, the surgical area was continued to be washed periodically with a solution containing gentamicin, rifampicin and povidone-iodine. Preoperative antibiotic prophylaxis included the administration of 1 g of vancomycin once a day and twice daily doses of 3rd generation cephalosporins. The patients used 750 mg of ciprofloxacin in tablet form twice a day for 7 days after discharge. None of the patients experienced any perioperative complications. Of the prostheses, 83 were single-piece (Promedon), 5 two-piece (Ambicor), 35 three-piece (AMS 700 CXP). After surgery, 12 patients had complications (9.7%), including penile pain in 5 patients, penoscrotal tenderness and itchy lesions, and infection of the surgical incision site that responded to medical therapy in 4 patients. In addition, 3 patients required the removal of the penile prosthesis, of which 1 was a three-piece (AMS 700 CXP) and 2 was a one-piece (Promedon). In all 3 patients, the reason for removing the prosthesis was uncontrolled infections. Moreover, one of these 3 patients had a history of radical prostatectomy and primary hypertension and the other two had a history of controlled DM. All 3 patients were smokers. These patients underwent both removal of the prosthesis and implantation of a new prosthesis with the same characteristics in the same session. No problem recurred in 3 patients who underwent salvage surgery. The use of the penile prosthesis was allowed 6 weeks after the second surgery. The duration of the post-discharge antibiotic regimen was extended up to 2 weeks. No problem was encountered during the 6-month follow-up (Table 3).

Table 1. Causes of erectile dysfunction.

Cause of ED (Doppler USG)	Bilateral Arterial Insufficiency	90/123	73.1%
	Mix Type Insufficiency	10/123	8.1%
	Normal (Other)	18/123	14.6%
	Left Arterial Insufficiency	5/123	4.0%

Table 2. Intraoperative approach.

Number	Mean	Standard deviation	Lowest	Highest	
Age	123	62	±9	36	73
Duration of ED	123	29	±32	12	180
Duration of the operation	123	70	±20	42	128
Follow-up time (months)	123	13	±5	6	24
Dilatation	123	12.1	±1.0	10.0	13.0

Table 3. Postoperative complications.

Complication	Total	12/123	9.7%
	Penile pain	2/123	1.6%
	Hematoma	3.27	2.4%
	Superficial Wound Infection	4/123	3.2%
	Removal of the prosthesis	3/123	2.4%

Discussion

It is common practice to immerse penile implants in antibiotic solution prior to implantation. One of the most important complications of penile prosthesis implantation is infection of the prosthesis. The most common infectious agents are Staphylococcus epidermidis, Proteus mirabilis, P. aeruginosa and Escherichia coli, respectively. Both the American Urological Association (AUA) and the European Association of Urology (EAU) have developed surgical prophylaxis guidelines for penile prosthesis operations. Prosthesis infection may be characterized by only pain without signs of infection, or may progress to penile necrosis and loss [12,13]. Its incidence varies between 1 and 10%. However, today the average incidence is between 1 and 3% [14,15,16]. During the first prosthetic surgeries, urologists used a number of solutions based on their previous clinical experience to provide protection from infection. However, no one has described a standard procedure. Antiseptic solutions and their associated concentrations have never been evaluated for their effectiveness. When faced with an implant infection, a salvage procedure has been accepted that involves immediate replacement of the infected implant after antiseptic washing of the implant cavities [8].

According to the protocol described by Mulcah, the infected prosthesis is first removed along with all its parts. The corpus cavernosum and the anatomical spaces containing the other parts of the implant can then be irrigated with kanamycin + bacitracin, hydrogen peroxide, vancomycin + gentamycin and povidone-iodine, and then again with hydrogen peroxide and kanamycin + bacitracin. Finally, the new prosthesis can be implanted in the same session [17].

In a review between 2003 and 2018, Pan et al recommended that body cavities and the scrotal pump area be washed with povidone-iodine for not less than 3 minutes, followed by irrigation with saline and antibiotic solutions. However, they did not recommend the active substance, concentration and method of administration of the antibiotic regimen [18].

In this study, we describe a new procedure that involves the use of a mixture of 2400 mg of gentamicin, 5000 mg of rifampicin and 500 cc of 10% povidone-iodine in a 1000 cc isotonic saline solution. The penile prosthesis and all its parts were placed in this mixture and waited until implantation. The surgical area was washed with solution before the incision and every 15 minutes thereafter. After corporotomy, corpus cavernosum was 3 times using this solution, and the penile prosthesis was implanted after prewashing. Penile prosthesis infection was seen in 3 patients who required revision surgery (3.2%). These patients underwent a salvage surgery in which the same procedures were repeated.

In a multicenter study, Henry et al. reported the detection of

positive cultures and visible bacterial biofilms on clinically non-infected inflatable penile prostheses in the majority of patients during revision surgery. They also showed that revision washout at revision surgery of inflatable penile prostheses for non-infectious reasons reduces the bacterial load on the implant capsule tissue [19].

Apart from all these classical methods, prosthesis manufacturers have recently produced prostheses coated with antibiotics (minocyclin+rifampicin) and that are able to absorb the antibiotic agent in the solution in which they are immersed, in order to reduce the rates of implant infection. Although implant infection remains a problem, recent advances in antibiotic-coated devices and abundant use of antiseptic irrigation have reduced its incidence [20,21].

On the other hand, in a recent study, the authors reported that the use of repeated antibiotic irrigations in revision surgeries can achieve infection rates comparable to those in patients undergoing primary prosthesis implantation surgery [22]. In our study, we performed irrigation with an antibiotic solution in patients who underwent primary surgery. In our study, all prostheses were irrigated with an antibiotic solution, regardless of whether they were coated with antibiotics. There were 3 patients who required revision surgery (2.4%).

Conclusion

Measures to prevent the formation of penile prosthesis infections, rather than their treatment, are of great importance. Although manufacturers produce antibiotic-coated prostheses, the development of infections is the most feared complication of penile prosthesis implantation. Our study on infections had a retrospective design. All penile prostheses to be implanted were not checked for antibiotic coating before surgery. No samples were taken for culture study during revision surgery. We believe that this study will shed light on more comprehensive studies on this subject, thanks to the new solution we have described.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

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